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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/507,442

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Edward A. Hunter

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EXAMINER

SKOWRONEK, KARLHEINZ R

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/507,442	Applicant(s) HUNTER ET AL.	
	Examiner KARLHEINZ R. SKOWRONEK	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Status

Claims 1-10 are pending.

Claims 1-10 have been examined.

Claims 1-10 are rejected.

Priority

This application accepted on 15 March 2006 as the 35 USC 371 filing of PCT/US03/07968, filed on 13 March 2003, and claims the benefit of US Provisional Application No. 60/363,889, filed on 13 March 2002.

Information Disclosure Statement

No information disclosure statements have been filed at this time.

The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a

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separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

Drawings

The drawings filed 13 September 2004 are acceptable.

Objections to the Specification

The use of the trademarks PENTIUM (p. 8, 19), WINDOWS (p. 9), NIKON (p.10, 19, 20), VISUAL C++ (p. 51), and MICROSOFT (p. 51) have been noted in this application. They should be capitalized wherever they appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-5 are directed to processes for measuring cell activity. The following analysis is taken from the guidance provided in the MPEP at 2104.IV, "Determine

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Whether the Claimed Invention Complies with 35 USC101". The claims are directed to processes. Here the claims are directed to the abstract idea of data manipulation. The processes do not recite a physical transformation of matter from one state to another. Giving the claims the broadest reasonable interpretation, the claims read on mental steps. In *Comiskey* (*In re Comiskey*, 84 USPQ2d 1670) the court established that "the application of human intelligence to the solution of practical problems is not and of itself patentable" (at 1680). In *Comiskey*, the court stated explicitly "mental processes - or processes of human thinking - standing alone are not patentable even if they have a practical application" (at 1679). The court in *Comiskey* stated, "Following the lead of the Supreme Court, this court and our predecessor court have refused to find processes patentable when they merely claimed a mental process standing alone and untied to another category of statutory subject matter even when a practical application was claimed" (at 1680). The court's recent decision in *In re Bilski* confirmed, "a process is patent-eligible under 35 USC 101 if it is tied to a particular machine or apparatus or if it transforms a particular article into a different state or thing" (*In re Bilski*, 88 USPQ at 1391, 2008). In the instant claims, the process is not tied to a class of statutory invention. The claims recite a "method executable by a computer" which is a field of use limitation and is insufficient to render the claims patent eligible. The preamble of the claim also recites the use of a specific machine in "an automated microscopy platform" in describing how the data that is manipulated by the method was collected. The recitation relates to extra solution activity. Output is insignificant post-solution activity and does not represent a significant tie to another category of invention. The court in

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Comiskey, stated “the court rejected the notion that mere recitation of a practical application of an abstract idea makes it patentable, concluding that ‘[a] competent draftsman could attach some form of post-solution activity to almost any mathematical formula’” citing *Flook* (437 U.S. at 586, 590). The recent decision in *Bilski* confirmed the court’s position regarding insignificant pre- or post-solution activity (i.e. insignificant extra-solution activity) as stated in *Comiskey* (see *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008) at p. 13-96-1397). Applicant is encouraged to consider the recent BPAI informative decisions *Exparte Langemyr* (No. 2008-1495 (28 May 2008)) and *Exparte Biliski* (No. 2002-2257 (26 September 2006)) for further clarification of the above grounds of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-5 and 6-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 9 recite the phrases “the first cellular material” (line 2 and 5 of claim 4; line 3 and 6 of claim 9) and “second cellular material” (line 3 and 5-6 of claim 4; line 4-6 in claim 9). The phrases make the metes and bounds of the claims indefinite because the claim from which each claim 4 and 9 depend recites a single cellular material. It is unclear which of the first or second cellular material refers to the recited cellular material of the reference claim. Alternatively, claims 4 and 9 lack the antecedent

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basis for the first and second cellular materials. Claims 5 and 10 are also rejected because they depend from claims 4 and 9, respectively, and thus contain the above issues due to said dependence.

As set forth below, claims 6-10 invoke 35 USC 112, Sixth Paragraph. The MPEP2181 (II) states, "If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112." In re Donaldson Co., 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc). In the instant case, the specification does not provide an adequate disclosure showing the structure, material or acts for these "means-plus-function" limitations, for reasons as set forth below. Therefore, applicant fails to particularly point out and distinctly claim the invention as required by the second paragraph of 35 USC 112, and one skilled in the art would not know what are meant by these "means-plus-function" limitations, and the metes and bounds of the claimed invention are thus unclear.

First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claims 6-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 6-10 are directed to a system for measuring cell activity. First, claims 6-10 recite limitations using the phrase "means for". Second, in claims 6-10 the recited limitations modify the "means for" phrases with functional language. For example, line 2 of claim 6 recites "means for segmenting cellular components in the image". Finally, the "means for" phrases of claims 6-10 are not modified by sufficient structure, material, or acts for achieving the functions of claims 6-10. On the basis of the previous three conditions in claims 6-10, the limitations of claims 6-10 are considered to invoke 35 USC 112, Sixth paragraph as set forth in MPEP 2181.

35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure...described in the specification and equivalents thereof." "If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language." *In re Donaldson Co.*, 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc).

In the instant case, the specification fails to set forth an adequate disclosure of what is meant by "means for segmenting cellular components in the image" and "means for measuring translocation of cellular material" as recited in claim 6-10.

Claims 6-10 are indefinite because the metes and bounds of the claimed means have not been pointed out particularly in the disclosure. The disclosure fails to show the

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recited means as in claims 6-10. The description fails to further describe the means for that perform the recited functions. The description does not set for the material or structure for the means as recited in claim 6-10. Thus, one of skill in the art would be reasonably doubt that the inventor, at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giuliano et al. (US PAT 6,416,959), in view of Lee et al. (US PAT 5,528,703), and in view of Sudbo et al. (Analytical Cellular Pathology, 21, p. 71–86, 2000).

The claims are directed to a method and system for measuring cell activity in which the cells in an image are segmented; separating segmented overlapping cells, and measuring the translocation of cellular material between a first and second region of the cell caused by an agent. In an embodiment, segmenting includes enhancing the contrast between the first and second compartments and the background. In an embodiment, separating includes tessellation.

Giuliano et al. shows a method and system for measuring cell activity by image analysis. Giuliano et al. shows the cells in an image are segmented (col. 21, line 50-52). Giuliano et al. shows the translocation of cellular material between a first and second region of the cell caused by an agent is measured (col. 25, 52-67). Giuliano et al shows the cellular material in a first region of interest is compared to the cellular material in a second region of interest (col. 18 line 13-46)

Giuliano et al. does not show separating segmented overlapping cells.

Lee et al. shows a method of identifying objects in images. Lee et al. shows cells that are overlapping in an image are separated (col. 5, line 38-52). Lee et al shows this has the benefit of reducing the impact of overlapping cells on parameter determination (col. 5, line 46-47).

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Giuliano et al. in view of Lee et al. does not show separating by tessellation.

Sudbo et al. is directed to a method of separating cells in an image using the tessellation techniques of Voronoi Diagram (VD) construction and Delaunay triangulation (figures 1 and 2; p. 73, col. 1-p. 74, col. 1). Sudbo et al. shows segmenting includes enhancing the contrast between any element to be detected and the background (p. 72, col. 2). Sudbo et al. shows the Voronoi Diagram is the most informative tool for exploring tissue structure.

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method and system for measuring cell activity of Giuliano et al. with the separation of overlapping cells of Lee et al. because Lee et al. shows doing so has the benefit of reducing the impact of overlapping cells on parameter determination. It would have been further obvious to one of ordinary skill in the art at the time of invention to modify the method and system for measuring cell activity of Giuliano et al. and separation of overlapping cells of Lee et al. using the tessellation technique of Voronoi Diagrams of Sudbo et al. because Sudbo et al. shows the Voronoi Diagram is the most informative tool for exploring tissue structure. It would have been further obvious to one of ordinary skill in the art at the time of invention to modify the method and system for measuring cell activity of Giuliano et al. and separation of overlapping cells of Lee et al. using the tessellation technique of Voronoi Diagrams of Sudbo et al. because all the claimed elements were known, in the prior art, and one skilled in the art could have combined the elements as claimed by known methods with no change in

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their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention.

Claims 4-5 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giuliano et al., in view of Lee et al., and in view of Sudbo et al. As applied to claims 1-3 and 6-8 above, and further in view of Pohl et al. (Pharmaceutical research, Vol. 16, No. 2, p. 327-332, 1999).

An embodiment of the claims is directed to measuring the fractional intensity of cellular materials and comparing the fractional intensities. In another embodiment, the claims are directed to segmenting that includes enhancing background and separating that includes tessellating.

Giuliano et al., in view of Lee et al., and in view of Sudbo et al. as applied to claims 1-3 and 6-8 above show a method of image analysis for measuring cell activity in response to an agent in which segmenting includes enhance contrast with the background and separating that includes tessellation.

Giuliano et al., in view of Lee et al., and in view of Sudbo et al. does not show the measurement of a fractionalized intensity.

Pohl et al. shows a measurement of fractional intensity. Pohl et al. shows the fractional intensity is the measure of fluorescence intensity of a region of interest divided the measure of total fluorescence intensity (p.330, col. 1). Pohl shows in figure 3 the successful use of fractional intensity to compare different regions of interest.

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It would have obvious to one of ordinary skill in the art at the time of invention to modify the method of image analysis for measuring cell activity in response to an agent of Giuliano et al., in view of Lee et al., and in view of Sudbo et al. as applied to claims 1-3 and 6-8 above with the fractional fluorescence intensity measurements of Pohl et al. because all the claimed elements were known, in the prior art, and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARLHEINZ R. SKOWRONEK whose telephone number is (571)272-9047. The examiner can normally be reached on 8:00am-5:00pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KARLHEINZ R SKOWRONEK/
Examiner, Art Unit 1631

14 April 2009